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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/813,872	03/30/2004	Dominique Charmot	29329-715.202	5573
56631	7590	03/21/2006	EXAMINER	
WILSON SONSINI GOODRICH AND ROSATI / ILYPSA, INC. 650 PAGE MILL ROAD PALO ALTO, CA 94304			YOUNG, MICAH PAUL	
			ART UNIT	PAPER NUMBER

1618

DATE MAILED: 03/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/813,872

Applicant(s)

CHARMOT ET AL.

Examiner

Micah-Paul Young

Art Unit

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 November 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,10,16,17,20-24,31,32 and 45-60 is/are pending in the application.
- 4a) Of the above claim(s) 45-60 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,10,16,17,20-24,31 and 32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgment of Papers Received: Amendment /Response dated 11/18/05.

Election/Restrictions

1. Newly submitted claims 45-60 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the new claims are drawn to a method of removing potassium ion from an animal while the product of the original claims can be used for simple drug delivery.
2. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 45-60 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 1,10,16,17,20-24,31 and 32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. As discussed above potassium-binding polymers are not mentioned in the

Art Unit: 1618

specification by name or exemplified by the examples. Potassium-binding polymers are never mentioned in the specification and are not exemplified in the examples. Only phosphate-binding polymers are described by the specification. Applicant has not provided sufficient disclosure to distinguish potassium-binding polymers from phosphate or any other ion binding polymers.

These new amendments represent new matter.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1,10,16,17,20,21,31,32 remain rejected under 35 U.S.C. 102(a, e) as being anticipated by Tyler (US 2004/0166156).

6. Tyler discloses a particle (tablet) comprising a core and a shell material (coating), see abstract. The particles target a solute as claimed, as they are for lowering serum phosphate levels in patients by removing the phosphate from the gastrointestinal tract, see page 1. The core includes the same polymers as recited in the specification as useful in the invention, e.g. polyallylamine, etc., which may be crosslinked with the same crosslinking agent as recited by applicant, e.g. epichlorohydrin, etc., see pg. 1-2 and pg. 2 [0019]. The cores include a non-metal material. The coating or shell material includes various polymers, including cellulose, etc. see

Art Unit: 1618

page 2 [0013]. The coating would be physically attached to the core, as it is coated thereon. The particles would inherently be expected to satisfy the functional limitations set forth in the claims, since the particles contain the same components, i.e. the same core polymers and are used for the same purpose. A compound and its properties cannot be separated. The particles are used for therapeutic methods, including removing toxins, by lower phosphates (to treat renal failure) and lowering cholesterol see page 1. Though the reference is silent to the specific removal of potassium ions, it is the position of the Examiner that these polymers would inherently possess these properties. The polymers recited by Tyler are relied upon for the purposes of the instant invention throughout the specification, and though not expressly recited, it remains the position of the Examiner that the polyallylamine polymers of Tyler would also bind potassium. These disclosures render the claims anticipated.

7. Claims 1,10,16,17,20,21,31,32 are rejected under 35 U.S.C. 102(a, e) as being anticipated by Simon (US 2005/0036983).

8. Simon discloses a particle (bead) comprising a core and a shell material (coating) see abstract, page 3 and example 1. The particles remove toxins from the body such as urea [0020]. The core includes polyallylamine, which is crosslinked with crosslinking agents; see [0020-0030]. The cores include non-metal materials, such as polymers. The coating or shell material include various polymers such as cellulose as well as enteric polymers such as crosslinked methacrylic polymers; see [0031]. The coating would be physically attached to the core, as it is coated thereon. The particles would inherently be expected to satisfy the functional limitations

Art Unit: 1618

set forth in the claims, since the particle contain the same components. For these reasons the claims remain anticipated by the claims.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

11. Claims 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Tyler (US 2004/0166156), Bandi (US 4,902,501) and Kataoka (US 6,881,484).

12. As discussed above Tyler teaches a coated tablet comprising a core and shell structure sued to remove toxins form the GI tract, specifically phosphates. The dosage forms can be used to treat patients suffering from various disorders including renal failure. The reference is silent to the specific sizes recited in the claims however size is a major consideration with regard to the shell and core particle.

13. Bandi teaches particle for the same use of Tyler and teaches that the particles may have a size of 5 microns, of 500 um; see column 2.

Art Unit: 1618

14. Kataoka teaches shell-core particles for pharmaceutical use that employ the same polymers claimed, see column 3. The reference particle sizes and shell thickness may vary and are optimized to be within the ranges recited in the claims, see column 3, line 45+.

15. It would have been obvious to optimize the size of the particles disclosed by Tyler and to be within the claimed ranges because it is known in the art particles size and shell thickness may be optimized to include the ranges as claimed to optimize various properties of the particles (disintegration times, amount of polymer, etc.) as shown by Bandi and Kataoka.

Double Patenting

2. Claims 1,10,16,17, and 20-24 of this application conflict with claims 3,4,14,15, and 18-22 of Application No. 10/814,749. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

3. Claims 1,10,16,17,20-24 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 3,4,14,15, and 18-22 of copending Application No. 10/814,749. Although the conflicting claims are not identical, they are not patentably distinct from each other because both set of claims recite pharmaceutical formulations comprising core-shell formulation comprising potassium-binding polymers that are

Art Unit: 1618

crosslinked. The formulations both have shells with thicknesses up to 50 microns. These claims would act as obviating art over each other.

4. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

16. Applicant's arguments filed 11/18/05 have been fully considered but they are not persuasive. Applicant argues that:

a. The amendments obviate and render moot the rejections.

17. Regarding this argument, it is the position of the Examiner that prior art of Tyler and Simon remain anticipatory over the claims. The claims present identical shell-core structures with identical polymers as those used throughout the specification for the same purposes of applicant, e.g. removing toxins from the GI tract. The amendment simply add functional limitations to the same polymers, reciting what the polymers should be capable of, however applicant has provided no evidence that the polymers recited by Tyler and Simon, and named throughout the specification would not be capable of these functional limitations. The claims will remain obviated and anticipated until such evidence can be presented for consideration.

Conclusion

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 1618

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

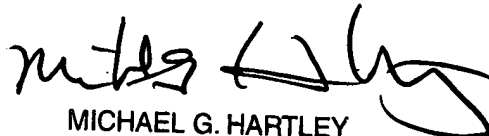
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 571-272-0608. The examiner can normally be reached on M-F 7:00-4:30 every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Micah-Paul Young
Examiner
Art Unit 1618

MP Young


MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER